**Reporting Unanticipated Problems, Adverse Events, and Serious or Continuous Non-compliance**

The PI or others involved in research projects will promptly (within 3 calendar days of the event) report to the IRB Chair or Coordinator any substantial changes in activities of the project that was approved by the IRB, any unanticipated problems, unexpected events, or any serious or continuing non-compliance with the study protocol.

The IRB Chair will immediately investigate the situation(s) and may take the following actions:

1. If the situation is severe, immediately place the study on "hold" until the MSU IRB can review the information and decide on a course of action.
2. Do not place the study on "hold," but refer the situation to the MSU IRB for review.
3. If the event posed minimal risk to the subject, deal with the matter administratively.

In cases referred to the MSU IRB, the IRB can:

1. Permanently close the study.
2. Request that a revised protocol be submitted which contains modified subject eligibility requirements and/or additional safety procedures.
3. Decide that the risk to the subject(s) was minimal and let the study proceed, with or without more frequent reviews.

All cases of serious or continuous noncompliance with study protocols will be reviewed by the MSU IRB, which may:

1. Permanently close the study.
2. Sanction the investigator(s) on all human subject research; sanctions may include suspensions for varying terms or permanent exclusion from participating in human subject research at MSU.
3. Institute oversight procedures on the study and/or all studies of the investigator(s).
4. Report to the MSU Office of Research Compliance and/or appropriate federal department and agency, if applicable.

08/01/2018